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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,108	09/29/2000	Lynn Joens	M0-4890	2035

157 7590 03/05/2002

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EXAMINER
ZEMAN, ROBERT

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/677,108	JOENS, LYNN	
	Examiner	Art Unit	
	Robert A Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *8-21 and 23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,22 and 26* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Groups I-III, Groups V and VI, Groups IX and X, Groups XIII-XV and Groups XVI and XVII share identical issues of the same class and subclass. This is not found persuasive because though the aforementioned groups share the same class and subclass, searches of said groups would not be coextensive in scope.

The requirement is still deemed proper and is therefore made FINAL.

However, in an effort to expedite prosecution of the instant application, Groups I and II are hereby rejoined.

Claims 1-26 are pending. Claims 8-21 and 23-25 have been removed from consideration. Claims 1-7, 22 and 26, to the degree they read on whole culture vaccines and inactivated culture vaccines, are currently under examination.

Specification

The use of the trademarks Polygen®, Carbopol®, Havlogen®, Carbigen®, Emulsigen®, Emulsigen Plus® and Emugen® has been noted in this application. Each should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

Claim 2 is objected to as reciting material drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a porcine from disease caused by *L. intracellularis*, does not reasonably provide enablement for methods of protecting other mammals, including man, from disease caused by *L. intracellularis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The above rejected claim is drawn to the prophylactic use of vaccine compositions comprising *L. intracellularis*. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments, in a reasonable model system. The specification, as filed, does not set forth that the claimed composition provides any sort of protective immunity in any model system that can be extrapolated to humans or mammals other than porcine. Applicant describes "prevention of diseases caused by *L.* intracellularis in porcine by treatment with inactivated *L. intracellularis* cultures" but fails to demonstrate said protection in any other animal system. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition is quite unpredictable. Given the

lack of success in the art, the lack of working examples, and the unpredictability of the generation of protective immunity, the specification, as filed, is not enabling for a method of protecting a porcine from disease caused by *L. intracellularis*, does not reasonably provide enablement for methods of protecting other mammals, including man, from disease caused by *L. intracellularis*.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 22 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 26 are rendered vague and indefinite by use of the phrase "antigens selected from the group consisting of 21 kDa, 31 kDa, 41 kDa, 43 kDa, 44 kDa, 60 kDa, 71 kDa, 115 kDa and > 115 kDa". It is unclear as to whether applicant is listing the molecular weights of antigens or merely naming the antigens.

Claims 1 and 26 are rendered vague and indefinite by the use of the term "producing antibodies". It is unclear what Applicant is claiming. Is Applicant claiming that the antigen "induces" the production of antibodies or actually produces the antibodies themselves?
Claim 6 and 7 contain the trademark/trade names Polygen®, Carbopol®, Havlogen®, Carbigen®, Emulsigen®, Emulsigen Plus® and Emugen®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim

does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe adjuvants and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Joens et al (U.S. Patent 5,610,059 – IDS-4).

The rejected claims are drawn to a proliferative ileitis vaccine comprising tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis*.

Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells (see examples 1 and 2). While Joens does not specifically disclose that said vaccine composition would induce the production of antibodies in a porcine that specifically binds the recited antigen fragments, the ability to produce said antibodies would be an inherent property of the vaccine composition since it comprises all the antigens of the *L. intracellularis*. Recitation of the term

"vaccine" in the instant claims is intended use and dos not distinguish over the composition of Joens et al. Therefore, since Joens et al. disclose all the limitations of the rejected claims it is anticipatory of said claims.

Claims 1-4, 22 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Joens et al (U.S. Patent 5,610,059 – IDS-4).

The rejected claims are drawn to a proliferative ileitis vaccine comprising tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis* and a method of using said vaccine to protect a mammal from the disease caused by *L. intracellularis*.

Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation.(see column 4, lines 6-16). Finally, Joens et al. disclose that said bacterin could be administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joens et al (U.S. Patent 5,610,059 – IDS-4).

The rejected claims are drawn to a proliferative ileitis vaccine comprising tissue culture grown *L. intracellularis* or an inactivated culture of *L. intracellularis* and optionally comprise an adjuvant. Said cultures being inactivated with heat, freeze/thaw or chemical treatment. Additionally, the rejected claims are drawn to a method of using said vaccine to protect a mammal from the disease caused by *L. intracellularis*.

Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* further disclosed to be inoculated into pigs in order to check its pathogenicity (see examples 1 and 2). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation. (see column 4, lines 6-16). Finally, Joens et al. disclose that said bacterin could be administered to pigs to "permit the pigs to mount an effective immune response against the agent (PPE).

Joens et al. differs from the instant claims in that they do not disclose the use of specific adjuvants (as recited in claims 6 and 7). However, use of said adjuvants is well known in the art. Since Joens et al. specifically disclose the use of the "bacterin" as a vaccine to prevent disease in pigs, it would have been obvious to one of skill in the art to combine said vaccine with an adjuvant to increase the immunogenicity of the vaccine composition. One would have had a high expectation of success since the use of claimed adjuvants is well known in the vaccine art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
February 27, 2002